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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,763	09/30/2003	Hoa Duc Nguyen		6270

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HIGH STANDARD PRODUCTS CORPORATION
SUITE 225
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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,763	NGUYEN ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/30/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "said". Correction is required. See MPEP § 608.01(b).

3. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In part b) of claim 1, the phrase "except for the stable isotope atoms" is indefinite since there is no indication in the claim that the internal standard contains isotope atoms. Part a) of claim 1 does not positively recite this. In part c) of claim 1, the phrase "extract said sample" is indefinite since it is really the oxime and oxime internal standard that are extracted or separated from the sample. See these same problems in claim 16.

In claim 2 of claim 1, the phrase "the isotope dilution mass spectrometric method" lacks antecedent basis. See this same problem in claim 17.

On line 3 of claim 6, the phrase "selected from a group comprising" should be changed to –selected from a group consisting of—so as to use proper Markush language. This same change should also be made in claim 21.

In claim 10, the phrase "said multiple aldehydes and/or ketones" lacks antecedent basis since claim 1 does not positively recite that the sample has multiple aldehydes and ketones therein. See this same problem in claim 25.

In claim 11, the phrase "said multiple labeled oxime internal standards" lacks antecedent basis since claim 1 does not positively recite that the internal standard is comprised of multiple labeled oximes. See this same problem in claim 26 with the phrase "said multiple labeled hydrazone internal standards".

In claim 12, the phrase "said stable isotope labeled oxime internal standard" lacks antecedent basis since claim 1 does not positively recite that the oxime internal standard is isotope labeled. See this same problem in claim 27 with the phrase "said stable isotope labeled hydrazone internal standard".

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 16-20 and 22-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Zurek et al (article from Fresenius' Journal of Analytical Chemistry).

Zurek et al teach of a method for determining acetaldehyde in tobacco smoke samples using isotope dilution liquid chromatography/mass spectrometry. The method comprises combining a sample of tobacco smoke containing acetaldehydes therein with an internal standard. The internal standard is formed by reacting an isotopically labeled acetaldehyde (i.e. labeled with $^{13}C_2$) with the alkylhydrazine N-methyl-4-hydrazino-7-nitrobenzofurazan (MNBDH) to form an isotopically labeled hydrazone internal standard. The sample of tobacco smoke is then reacted with MNBDH in a cartridge to convert the acetaldehyde in the sample to a hydrazone of identical structure as that of the hydrazone internal standard, except without the stable isotope atoms. The labeled hydrazone internal standard and the unlabeled hydrazone acetaldehyde are then extracted from the sample by high pressure liquid chromatography (HPLC), and then analyzed by mass spectrometry. The MNBDH reacted with the aldehydes in the tobacco smoke sample is a methylhydrazine that has the ability to react with multiple aldehydes such as formaldehyde and acetaldehyde. Zurek et al teach that the method is very selective for the quantification of aldehydes in tobacco smoke. In addition, no conversion of the stable isotope labeled hydrazone internal standard to its corresponding non-labeled hydrazone compound occurs during the converting of the sample to a hydrazone compound. See the abstract, the second full paragraph on page 396 and page 397 of Zurek et al.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zurek et al (from Fresenius' Journal of Analytical Chemistry) in view of Zurek et al (article from Analyst). For a teaching of Zurek et al ((from Fresenius' Journal of Analytical Chemistry), see previous paragraphs in this Office action. Zurek et al (from Fresenius' Journal of Analytical Chemistry) fail to teach that the isotope used to label the internal standard can be deuterium.

Zurek et al (article from Analyst) teach of a method for the quantification of carbonyls such as aldehydes and ketones in air samples by combining the sample with an isotopically labeled internal standard. The internal standard comprises aldehydes and ketones that have been reacted with isotopically labeled 2,4-dinitrophenylhydrazine (DNPH) to form labeled hydrazones. The isotope used to label the hydrazones is deuterium. The aldehydes and ketones in the sample are also converted to an unlabeled hydrazone by reaction with DNPH. The hydrazones are then extracted from the sample using HPLC and analyzed by mass spectrometry. See pages 1291and 1292 in Zurek et al (article from Analyst).

Based upon the combination of the two articles by Zurek et al concerning the detection of aldehydes and ketones in air samples, it would have been obvious to one of ordinary skill in the

art at the time of the instant invention to label the internal standard taught by the primary reference to Zurek et al with the commonly used isotope deuterium since the secondary reference to Zurek et al teaches that this isotope can be used to effectively label an internal standard used in a method to detect aldehydes and ketones by isotope dilution mass spectrometry, which is the same method used by the primary reference to analyze aldehydes in tobacco smoke samples.

10. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruenner et al (article from Analytical Biochemistry) in view of Ludeman et al (article from the Journal of Pharmaceutical Sciences, see abstract).

Bruenner et al teach of a method for the determination of aldehydes in biological tissues and fluids using gas chromatography/stable isotope dilution mass spectrometry. The method serves to determine the aldehydes hexanal, nonanal and 4-hydroxy-2-nonenal. The method comprises combining a biological tissue or fluid sample with isotopically labeled internal standards for the aldehydes including deuterated hexanal, deuterated nonanal and deuterated 4-hydroxy-2-nonenal. The sample is also derivatized by reacting the aldehydes therein with hydroxylamine hydrochloride (i.e. an alkoxylamine) to form oxime derivatives of the aldehydes. The samples are then extracted using gas chromatography and analyzed by mass spectrometry. Bruenner et al teach that the internal standards are identical to the aldehydes to be detected in the sample except for the presence of the deuterium labels. Bruenner et al teach that simultaneous quantitation of several aldehydes by GC/MS is achieved using the oxime derivatives and deuterated analogs as standards. See the abstract and pages 214-215 of Bruenner et al. Bruenner et al fail to teach that the isotopically labeled internal standards in the method can be oxime

derivatives of the aldehydes to be detected in the sample having an identical structure to the oxime aldehydes with the exception of stable isotope atoms therein.

Ludeman et al (see abstract) teach of a method for the quantitative analysis of the cyclophosphamide metabolites 4-hydroxycyclophosphamide and aldophosphamide. The method comprises derivatizing the metabolites with a hydroxylamine compound to convert the metabolites to aldehyde oximes. Ludeman et al teach that the oxime derivatives of the metabolites are then analyzed using gas chromatography/mass spectrometry (GC/MS). Ludeman et al also teach that each oxime compound is synthesized with deuterium in the chloroethyl moieties for use as internal standards in the GC/MS analysis. Therefore, Ludeman et al teach that the internal standards have the same oxime structure as the metabolites to be detected in the method except for the presence of stable isotope atoms.

Based upon a combination of Bruenner et al and Ludeman et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use isotopically labeled oxime internal standards in the aldehyde quantification method taught by Bruenner et al in place of the isotopically labeled aldehyde internal standards since Bruenner et al teach that the internal standards should be identical to the analytes to be detected with the exception of the deuterium labels, and the aldehydes detected in the method of Bruenner et al are present in the form of an oxime derivative, and Ludeman et al teach that oxime derivatives of compounds being detected using an isotope dilution mass spectrometry method should have internal standards therein that are also oxime derivatives that have the identical structure to the compounds with the exception of isotope atoms. It also would have been obvious to one of ordinary skill in the art to use any type of known alkoxylamine compound such as

methoxylamine or benzyloxyamine to convert the aldehydes in the samples analyzed in the method taught by Bruenner et al to oxime derivatives since each can equivalently perform the same function of converting aldehydes to oximes.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Zurek et al (from the Journal of Chromatography), van Kuijk et al and Kingston (WO 02/060565) who teach of isotope dilution mass spectrometry methods.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

December 8, 2006

Maureen M. Wallenhorst
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GROUP [redacted] 1700